

**PATENT** 24730-7012833001 (PC10247C) /

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE	
In re the Application of:	) Confirmation No.: 7185
Jonathan S. Stinson	) Oroup Art Unit: 3738
Serial No.: 09/852,541	) ) <b>Examiner:</b> Cheryl L. Miller
Filed: May 10, 2001	)
For: NEUROANEURYSM OCCLUSION AND DELIVERY DEVICE AND METHOD OF USING SAME	) ) ) _)
APPEAL BRIEF TRANSMITTAL	
Mail Stop Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
Sir,  Transmitted herewith is Appeal Brief identified application.	(24 pages) in triplicate, for the above-
The items checked below are approp	oriate.
<ul> <li>Appeal Brief Fee:</li> <li>□ Large Entity Fee of \$500.00; or</li> <li>□ Small Entity Fee of \$250.00.</li> <li>□ Applicant(s) claim Small Entity Status under 37 CFR § 1.27.</li> </ul>	
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Please charge Bingham McCutchen's Deposit Account No. **50-2518** in the amount of \$500.00.

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By:

Dated: May <u>13</u>, 2005

Respectfully submitted, BINGHAM McCUTHEN LLP

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## BIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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For: NEUROANEURYSM OCCLUSION

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**Group Art Unit: 3738** 

Examiner: Cheryl L. Miller

#### **APPEAL BRIEF-CFR 1.192**

ATTN: Board of Patent Appeals and Interferences

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Brief is in furtherance of the Notice of Appeal filed herewith, and contains the following items in the order indicated below, as required by C.F.R. §1.192:

Real Party in Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary of Invention

VI. Issues

VII. Grouping of Claims

VIII. Arguments

IX. Appendix of Claims Involved in the Appeal

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### I. Real Party in Interest

The real party in interest in this appeal is Schneider (USA) Inc., a corporation organized under the laws of Minnesota.

## II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

#### III. Status of Claims

This application includes claims 1-106. Of these claims, claims 33 and 68-106 are pending, and the remaining claims 1-32 and 34-67 have been cancelled. All pending claims stand rejected, leaving no claims allowed. The claims on appeal are claims 33 and 68-106.

## IV. Status of Amendments

All amendments have been entered.

## V. Summary of Invention

The present inventions are particularly well suited to medical procedures where it is desired to deliver vaso-occlusive devices, while allowing the delivery device itself to be easily withdrawn from the patient without disturbing the placement of the vaso-occlusive devices. In its broadest sense, the invention, as defined in the claims on appeal, is directed to an occlusion device delivery system that includes a tubular body, such as a catheter, a releasably deployable occlusion device, such as a self-expanding stent, positioned on the distal end of the tubular body, and a bioabsorbable or

dissolvable distal tip member fixedly secured to the distal end of the tubular body. The distal tip member may be configured to remain fixedly secured to the tubular body and/or remain intact during the entire bioabsorption or dissolution process. In this manner, the distal tip member, when dissolved to a smaller profile, may proximally pass through the deployed occlusion device when the tubular body is removed from the patient. The distal tip member may also be configured to allow deployment of the occlusion device without hindrance prior to undergoing bioabsorption or dissolution. Although it should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of the preferred embodiments in order to aid in further understanding the inventions.

Fig. 3 illustrates a basic embodiment of an occlusion device delivery system 8, which generally includes a tubular body 10, a bioabsorbable or dissolvable distal tip 20 mounted to the distal end of the tubular body 10, an occlusion device 50 mounted to the distal end of the tubular body 10, and an exterior tube 15 to maintain the occlusion device 50 in an undeployed or collapsed state until it is ready to be deployed. As can be seen in Fig. 3, the respective profiles of the distal tip 20 and exterior tube 15 are the same so that there is a smooth transition between the distal tip 20 and exterior tube 15 in order to facilitate introduction of the delivery system 8 through the vasculature of the patient. As can be seen in Fig. 4, the exterior tube 15 can be proximally moved relative to the tubular body 10 to begin deploying the occlusion device 50. Significantly, because the distal tip 20 is the same size as the exterior tube 15, the distal tip 20 will generally be larger than the distal opening in the occlusion device 50, as illustrated in Fig. 4. Also, the distal tip 20 is located distally of the occlusion device 50, so that it

does not hinder its deployment. Fig. 5 illustrates full deployment of the occlusion device 50. As illustrated, the profile of the distal tip 20 has been substantially reduced due to the bioabsorption or dissolution process, and has a size that can now pass through the distal opening of the fully deployed occlusion device 50. As such, the tubular body 10 with the distal tip 20 can be withdrawn, leaving the deployed occlusion device 50 in place, as illustrated in Fig. 6.

#### VI. Issues

- A. Whether claims 33 and 68-106 are unpatentable under 35 U.S.C. §102(e), as being anticipated by U.S. Patent No. 5,830,217 ("Ryan").
- B. Whether claims 33, 68-69, 72-82, 85-94, and 97-106 are unpatentable under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,603,698 ("Roberts").
- C. Whether claims 33, 68-69, and 72-79 are unpatentable under 35 U.S.C. §103, as being obvious over Roberts.

## VII. Grouping of Claims

Appellant believes that the follogwing groups of claims are separately patentable from each other:

#### For Rejection A:

- 1. Claims 33, 70-72, 75-79, and 101
- 2. Claim 68
- 3. Claim 69
- 4. Claim 73

- 5. Claim 74
- 6. Claim 104
- 7. Claims 80, 83-85, 87-91, and 102
- 8. Claim 81
- 9. Claim 82
- 10. Claim 86
- 11. Claim 105
- 12. Claim 92, 95-100, and 103
- 13. Claim 93
- 14. Claim 94
- 15. Claim 106

## For Rejection B:

- 1. Claims 33, 69, 72-79, and 101
- 2. Claim 68
- 3. Claim 104
- 4. Claims 80, 82, 85-92, 94, 97-100, 102, and 103
- 5. Claims 81 and 93
- 6. Claims 105 and 106

## For Rejection C:

- 1. Claims 33, 69, 72-79, and 101
- 2. Claim 68

### VIII. Arguments

#### Rejection A

Appellant respectfully submits that the Examiner erred in rejecting claims 33 and 68-106 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,830,217 ("Ryan"), since Ryan does not disclose each and every element required by these claims.

Ryan is directed to a stent delivery system that includes a catheter 3, a stent 1 carried by the distal end of the catheter 3, and a bioabsorbable hollow capsule 15 mounted around the distal end of the stent 1 at a location proximal to the distal tip of the catheter 3. When the stent 1 is delivered to a target site, the capsule 15 dissolves and falls off of the stent 1, at which point the stent 1 can be expanded and deployed without hindrance by the capsule 15. Significant to the present inventions, the capsule 15 is not a distal tip member, is not configured to remain intact, does not remain fixedly secured to the catheter 3 during the bioabsorption process, and hinders deployment of the stent 1 before the bioabsorption process is undergone.

## Claims 33, 68-79, 101, and 104

Independent claim 33 requires the bioabsorbable or dissolvable distal tip member to distally extend beyond the distal extremity of the tubular body. The Examiner had characterized the distal tip 5 of the catheter 3 of Ryan as being the distal extremity of the claimed tubular body. Based on an assumption that the distal tip 5 can be entirely contained within the capsule 15, the Examiner concluded that the capsule 15, as the claimed distal tip member, distally extends beyond the distal extremity of the

tubular body. (Final Office Action, dated February 24, 2005, page 2, lines 10-14; paragraph bridging pages 4 and 5). Appellant disagrees.

Ryan does not disclose that the entire distal tip 5 can be entirely contained within the capsule 15. Rather, Ryan merely discloses that the <u>balloon</u> may peak out of the capsule (see col. 4, lines 46-47). Ryan states nothing about whether the catheter tube 3 may permissibly peak out of the capsule. In fact, the catheter tube 3 is disclosed and illustrated as distally extending out from the capsule in all cases. Thus, the distal tip of the tubular body 3, which forms a part of the distal tip 5 of the catheter 3, extends distally from the capsule 15, and thus, it logically follows that the capsule 15 (assuming that it is the claimed distal tip member as the Examiner indicates) does not distally extend from the distal tip 5 of the catheter 3 (assuming that it is the distal extremity of the claimed tubular body as the Examiner indicates) Simply stated, a brief review of Figs. 2-5 makes it clear that the capsule 15 is indeed proximal to the distal extremity of the tubular body 3.

If it is the Examiner's position that the capsule 15 distally extends from the distal tip 5 of the catheter 3 merely because the capsule 15 contains a single component of the distal tip 5 (i.e., the balloon) that is proximal to the capsule 15, such an interpretation does not comport with a fair reading of what a distal extremity of a tubular body is, which can be defined as the distal-most point or portion of the tubular body. In this case, the distal-most point or portion of the catheter 3 is the distal tip of the tubular body 3, which clearly is distal to the capsule 15 in all embodiments. To construe the claims in accordance with the Examiner's construction would lead to the anomalous

result that any point along a catheter body, including the proximal end, could be considered the distal extremity of the catheter body.

Thus, Appellant respectfully believes that independent claim 33, as well as the claims depending therefrom (claims 68-79, 101, and 104), are patentable over Ryan. Some of the dependent claims recite additional patentable features, as discussed immediately below.

Claim 68 requires the distal tip member to include a guidewire lumen. The Examiner indicated that the capsule 15 of Ryan includes a perforation for the guidewire 4 (see Final Office Action, page 6, lines 11-12). However, a perforation is simply not a lumen, which can be defined as a bore—not a hole.

Claim 69 requires the distal tip to be solid. The Examiner indicated that the capsule 15 can be composed of a solid material (see Final Office Action, page 6, lines 13-14) However, claim 69 does not require that the distal tip member be composed of a solid material. Claim 69 requires that the distal tip member be solid. In contrast, the capsule 15 of Ryan is completely hollow.

Claim 73 requires the distal tip member be configured to remain disposed on the distal portion of the tubular body during the entire bioabsorption or dissolution process. The Examiner indicated that the capsule 15 is configured to remain on the tubular body 3 during the entire bioabsorption or dissolution process (see Final Office Action, page 6, lines 18-20) However, there is no such disclosure in Ryan, and in fact, the capsule 15, being hollow, would inevitably fall off the catheter 3 during the bioabsorption or dissolution process.

Claim 74 requires the distal tip member to bioabsorb or dissolve to a smaller profile, so that it can proximally pass through a distal opening in the occlusion device when the tubular body is displaced in the proximal direction. The Examiner indicated that the capsule 15 is configured to proximally pass through the distal opening of the stent 1 when the capsule 15 is in a smaller profile (see Final Office Action, paragraph bridging pages 6 and 7) However, the capsule 15 is not disclosed in Ryan as being capable of passing through the distal opening of the stent 1, and in fact, is not designed to do so, since it is actually mounted around the outside surface of the stent 1. The Examiner had stated that some of the capsule 15 will be left on the catheter after it has dissolved. For the reasons stated below with respect to independent claim 92, any residual matter left behind after the capsule 15 has fallen off cannot be fairly considered a distal tip member.

Claim 104 requires the distal tip member be configured for remaining intact during the bioabsorption or dissolution process. The Examiner indicated that the capsule 15 is configured for staying intact during the entire dissolution or bioabsorption (see Final Office Action, page 7, lines 16-17). However, the capsule 15 is not disclosed in Ryan as being configured for remaining intact during the bioabsorption or dissolution process, and would likely not be capable of doing so due to its hollow structure.

Thus, the additional patentable features recited in 68, 69, 73, 74, and 104 provide a further basis for the patentability of these claims over Ryan.

# Claims 80-91, 102, and 105

Independent claim 80 requires the distal tip member be configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorpotion

or dissolution process, and be configured to not hinder deployment of the occlusion device prior to undergoing bioabsorption or dissolution. The Examiner indicated that some of the material used to form the capsule 15 will remain on the tubular body 5 at all times, and thus, some of the tip will remain on the tubular body 5 at all times (see Final Office Action, page 3, lines 3-8). However, to the extent that any residual material is left on the catheter after the capsule 15 falls off, it cannot be fairly said that such residual material is the distal tip member. Rather, to the extent that the capsule 15 can be considered a distal tip member at all, the capsule 15 is not a distal tip member that is configured to remain fixedly secured to the distal end 5 of the catheter 3 during the entire bioabsorption or dissolution process, since the capsule 15, in main, would inevitably fall of the catheter 3.

Despite the fact that one of the disclosed purposes of the capsule 15 is to prevent deployment of the stent 1 until it partially or completely dissolves, the Examiner also indicated that the capsule 15 would not hinder deployment of the stent 1, pointing to various examples in Ryan where the deployment of stent 1 is achieved after the capsule 15 has been fully or partially dissolved (see Final Office Action, page 2, lines 14-17; page 5, lines 11-13). Clearly, in these examples, the capsule 15 is undergoing a bioabsorption or dissolution process, and thus, at this point, the ability of the capsule 15 to hinder or not hinder deployment of the stent 1 is irrelevant, since claim 80 inherently requires inquiry as to whether deployment of the stent 1 is hindered be made prior to the start of the bioabsorption or dissolution process.

Although the Examiner also indicated that Ryan discloses deployment of the stent 1 prior to the dissolution process (see final Office Action, page 2, lines 17-19;

page 5, lines 15-19), just because the stent 1 is capable of deploying does not necessitate a finding that such deployment was unhindered, as previously discussed in the amendment and response, dated December 14, 2004. Indeed, one would have to conclude that the undissolved capsule 15 would necessarily hinder deployment of the stent 1 by virtue of it being coated on the stent 1 as well as the portion of the catheter from which the stent 1 is designed to deploy. That is, there is no doubt that more pressure has to be applied by the balloon to expand the stent 1 in the case where the undissolved capsule 15 is used to constrain the stent 1 than in the case where the undissolved capsule 15 is non-existent, and thus, it must be concluded that the undissolved capsule 15 hinders deployment of the stent 1. The fact that the capsule 15, which is designed to constrain the stent 1, barely covers the stent 1 is of no import, since any portion of that bridges the stent 1 and catheter body 5 will naturally hinder deployment of the stent 1.

The Examiner also points to the Fig. 4 embodiment, wherein a polysaccharide mass 16 is used to attach the stent 1 to the balloon (see Final Office Action, page 2, line 19 to page 3, line 2). However, not only is such mass 16 not a distal tip member, the mass 16 is used to glue the stent 1 to the balloon, such that expansion of the stent 1 would necessarily require fracturing of the glue prior to the dissolution process, thereby hindering deployment of the stent 1.

Thus, Appellant respectfully believes that independent claim 80, as well as the claims depending therefrom (claims 81-91, 102, and 105), are patentable over Ryan. Further, the additional patentable features of claims 81, 82, 86, and 105 provide a

further basis for the patentability of these claims over Ryan, as discussed above with regard to claims 68, 69, 74, and 104.

## Claims 92-100, 103, and 106

Independent claim 92 requires the distal tip member be configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorption or dissolution process, so that the distal tip member may proximally pass through the distal opening of the deployed occlusion device when the tubular body is displaced in a proximal direction.

In contrast, the capsule 15 of Ryan is not disclosed as remaining fixedly secured to the distal end 5 of the catheter 3 during the entire bioabsorption or dissolution process, so that the capsule 15 may proximally pass through the distal opening of the deployed stent 1 when the catheter 2 is displaced in the proximal direction. In fact, as previously discussed above with respect to independent claim 80, the main of the capsule 15 will inevitably fall off of the catheter 3. In addition, to the extent that it is found that the capsule 15 does remain on the catheter 2, there is no disclosure, express or inherent, that such capsule 15, when partially dissolved, will be configured to pass through the distal opening of the stent 1, especially since the capsule 15 is mounted around the outer surface of the stent 1.

Thus, Appellant respectfully believes that independent claim 92, as well as the claims depending therefrom (claims 92-100, 103, and 106), are patentable over Ryan. Further, the additional patentable features of claims 93, 94, and 106 provide a further basis for the patentability of these claims over Ryan, as discussed above with regard to claims 68, 69, and 104.

#### Rejection B

Appellant respectfully submits that the Examiner erred in rejecting claims 33 and 68-106 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,603,698 ("Roberts"), since Roberts does not disclose each and every element required by these claims.

Roberts is directed to a stent delivery system that comprises a catheter 4, a stent 14 positioned at the distal end of the catheter 4, an atraumatic tip 26 positioned proximal to the distal tip of the catheter 4, and a protective sheath 20 for covering and maintaining the stent 14 within its undeployed state. The protective sheath 20 can be proximally displaced to allow the stent 14 to self-expand. The atraumatic tip 26 is configured for being slid off of the distal end of the catheter 4 to facilitate withdrawal of the catheter 4 from the patient. Significant to the present inventions, the atraumatic tip 26 does not distally extend from the distal extremity of the catheter 4, and is not configured for remaining fixedly secured to the catheter 4 during the bioabsorption process, but rather is designed to be selectively slid off of the catheter 4 after the stent 14 has been deployed.

# Claims 33, 68, 69, 72-79, 101, and 104

Independent claim 33 requires the bioabsorbable or dissolvable distal tip member to distally extend beyond the distal extremity of the tubular body. The Examiner interpreted the distal end of the catheter section 10, rather than the distal end of the catheter section 8, to be the distal extremity of the catheter body 4 (see Final Office Action, page 7, line 19 to page 8, line 2).

However, the catheter body 4 clearly includes both the proximal catheter section 10 and the distal catheter section 8, and thus, based on a reasonable claim construction, it is the distal extremity of the distal catheter section 8, and not the distal extremity of the proximal catheter section 10, that represents the distal extremity of the catheter body 4. The fact that the respective catheter sections 8 and 10 are composed of different material is of no import, since the catheter body 4 acts as a single body. It is noted that catheter bodies are often composed of materials that differ along their lengths, and the distal extremities of the distal-most catheter sections are invariably referred to as the distal extremities of the catheter bodies. It would be completely contrary to the ordinary and accustomed meaning of the language "distal extremity of a tubular body" to interpret it to include a point that is in the middle of the tubular body merely because the tubular body is composed of different materials. As such, the atraumatic tip 26 does not distally extend from the distal extremity of a tubular body.

To the extent that it is the Examiner's position that the catheter section 10 is a structurally distinct element separate from the catheter section 8 prior to assembly, and thus, would be considered a tubular body by itself, Appellant contends that the identification of a catheter tube within the Roberts device must be made after the Roberts device is assembled, since claim 33 requires a delivery system—as opposed to a kit that is subsequently assembled.

Independent claim 33 further requires the bioabsorbable or dissolvable distal tip member be fixedly secured to the distal portion of the tubular body. As discussed below with respect to independent claims 80 and 92, the distal tip 26 of the Roberts device is not fixedly secured to the catheter body 4.

Thus, Appellant respectfully believes that independent claim 33, as well as the claims depending therefrom (claims 68, 69, and 72-79, 101, and 104), are patentable over Roberts. Some of the dependent claims recite additional patentable features, as discussed immediately below.

Claim 68 requires the distal tip member to include a guidewire lumen. The Examiner indicated that the tip member 26 of Roberts includes a guidewire lumen 35 (see Final Office Action, page 9, lines 15-16). However, the lumen 35 contained in the tip member 26 is not a guidewire lumen, but rather a lumen through which the entire catheter body 4 passes.

Claim 104 requires the distal tip member be configured for remaining intact during the bioabsorption or dissolution process. The Examiner indicated that the tip member 26 of Roberts is configured to not slide off during dissolution or bioabsorption (see Final Office Action, page 9, line 19 to page 10, line 2). However, the tip member 26 is capable of sliding off the catheter body 4 using a minimal amount of force, and therefore, is configured for sliding off the catheter body 4.

Thus, the additional patentable features recited in claims 68 and 104 provide a further basis for the patentability of these claims over Roberts.

Claims 80-82, 85-94, 97-100, 102, 103, 105, and 106

Independent claims 80 and 92 each requires the bioabsorbable or dissolvable distal tip member be fixedly secured to the distal portion of the tubular body. The Examiner indicated that the tip member 26 is fixedly secured to the catheter body 4 by means of a friction fit, and therefore is configured to remain fixedly secured to the

catheter body 4 until it is forcibly removed (see Final Office Action, page 3, lines 10-14).

Appellant disagrees.

As previously discussed in the amendment and response, dated December 14, 2004, the ordinary and accustomed meaning of the claim language "fixedly secured to the distal portion of the tubular body" means that the distal tip 26 of the Roberts device be secured to the catheter body 4 firmly in position, or secured to the catheter body 4 in a stationary, determined, established, or set manner, or secured to the catheter body 4 such that it is not subject to change or variation or is constant. The instant specification discloses various manners of fixedly securing the distal tip member to a tubular body (e.g., adhesive bonding, injection molding, ultrasonic or fusion welding, etc) (see col. 10, line 22 to col. 11, line 16), and thus, supports such an interpretation. In contrast, because the tip member 26 is configured to be removed from the catheter body 4 using an insignificant amount of force (see col. 6, lines 10-13), the tip member 26 cannot be reasonably construed to be fixedly secured to the catheter body 4.

The Examiner indicated that unless a force is applied, the tip 26 will remain on the catheter body 4, and is thus configured to remain on the catheter body 4 (see Final Office Action, page 3, lines 12-13, lines 16-19; page 8, lines 17-18). The Examiner further indicated that the tip member 26 is selectively dislodgeable, and therefore, it can remain secured to the catheter body 4 (see Final Office Action, page 3, lines 19-21). However, to the extent that the tip member 26 is secured to the catheter body 4 or otherwise has the capability of remaining on the catheter body 4, it is not fixedly secured. Appellant contends that by interpreting the claim language "fixedly secured" to include the arrangement where an object is merely secured to another object using any

means or merely remains on the object, the language "fixedly" has been improperly ignored. That is, the term "fixedly" qualifies the term "secured." Thus, the language "fixedly secured" must mean something more than being merely secured or having the capability of remaining on an object. Although it is true that "removal of the tip 26 from the body 4" is a method step, as indicated by the Examiner (see Final Office Action, page 3, line 19 to page 4, line 3), Appellant is not claiming a method step. Rather, Appellant is claiming an arrangement or relationship between a distal tip member and a tubular body; namely, that the distal tip member is fixedly secured to the tubular body.

The Examiner further indicated that the outer sheath 22 and stop 33 fixedly secure the distal tip 26 to the catheter body 4 (see Final Office Action, page 8, lines 5-6). However, the outer sheath 22 and stop 33 do not secure the distal tip 26 to the catheter body 4, but rather prevent the distal tip 26 from axially moving in the proximal direction along the catheter body 4 (see col. 6, lines 16-29). The sheath 30 does not prevent the distal tip 26 from moving in the distal direction, and thus, does not fixedly secure the distal tip 26 to the catheter body 4. In addition, because the outer sheath 22 is designed to slide along the body 4, it cannot fixedly secure the distal tip 26 to the catheter body 4.

Thus, Appellant respectfully believes that independent claims 80 and 92, as well as the claims depending therefrom (claims 81, 82, 85-91, 93, 94, 97-100, 102, 103, 105, and 106), are patentable over Roberts. Further, the additional patentable features of claims 81 and 93 and claims 105 and 106 provide a further basis for the patentability of these claims over Ryan, as discussed above with regard to claims 68 and 104.

#### Rejection C

Appellant respectfully submits that the Examiner erred in rejecting claims 33, 68, 69 and 72-79 under 35 U.S.C. §103 as being obvious over Roberts, since Roberts does not disclose, teach, or suggest the combination of elements required by these claims.

In particular, the Examiner indicated that it would have been obvious to place the distal tip 26 of Roberts at the distal extremity 8 of the catheter body 4, "since it has been held that a mere relocation of parts of an invention involves only routine skill in the art." (In re Japikse, 86 USPQ 70) (see Final Office Action, page 11, lines 3-15). However, Japikse does not state this. Rather, Japikse stands for the proposition that the mere relocation of a part would not result in an invention if "the operation of the device would not thereby be modified." (See Japikse at 73). In this case, moving the distal tip 26 to the distal tip of the catheter section 8 would indeed modify the operation of the Roberts device, since it would effectively eliminate the flexible distal end 8, which serves to allow the catheter body 4 to easily flex when challenged by a lumen wall for atraumatic advancement (see col. 4, lines 13-19).

Significantly, there must be some suggestion in the prior art to modify a prior art reference in order to find that a claim is obvious. In this case, there is no suggestion to modify the Roberts device, such that the distal tip 26 distally extends from a distal extremity of the catheter body 4. In addition, there is no suggestion in the prior art to modify the Roberts device, such that the distal tip 26 is fixedly secured to the catheter body 4, and in fact, Roberts specifically teaches away from this arrangement, since the Roberts device operates on the principle that the distal tip 26 is to be slid off of the catheter body 4 after deployment of the stent 14.

PATENT 24730-7012833001 (PC10247C)

Thus, Appellant respectfully believes that independent claim 33, as well as the claims depending therefrom (claims 68, 69 and 72-79) are patentable over Roberts. In addition, claim 68 recites an additional patentable feature not disclosed, taught, or suggested in Roberts, and discussed above.

By:

Michael J Bolan Reg. No. 42,339

Respectfully submitted, Bingham McCutchen LLP

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## IX. Appendix of Claims Involved in the Appeal

- 33. An occlusion device delivery system comprising:
- a tubular body including a distal portion and a distal extremity;
- a releasably deployable occlusion device positioned on the distal portion of the tubular body; and

a distal tip member fixedly secured to the distal portion of the tubular body, wherein the distal tip member distally extends beyond the distal extremity of the tubular body, the distal tip member including at least a partially bioabsorbable or dissolvable material.

- 68. The delivery system of claim 33, wherein the distal tip member further comprises a guidewire lumen.
  - 69. The delivery system of claim 33, wherein the distal tip member is solid.
- 70. The delivery system of claim 33, wherein the distal tip member is configured to bioabsorb or dissolve in less than about 15 minutes in vivo.
- 71. The delivery system of claim 33, wherein the distal tip member is configured to bioabsorb or dissolve within a range of about 5 to about 10 minutes in vivo.
- 72. The delivery system of claim 33, wherein the distal tip member is configured to either bioabsorb or dissolve to a smaller profile.
- 73. The delivery system of claim 72, wherein the distal tip member is configured to remain disposed on the distal portion of the tubular body during the entire bioabsorption or dissolution process.
- 74. The delivery system of claim 72, wherein the occlusion device comprises a distal opening when deployed, and the distal tip member, in the smaller profile, is

configured to proximally pass through the distal opening of the deployed occlusion device when the tubular body is displaced in a proximal direction.

- 75. The delivery system of claim 33, wherein the distal tip member is configured to bioabsorb or dissolve substantially away.
- 76. The delivery system of claim 33, wherein the distal tip member has a substantially smooth transition at an edge of the tubular body.
- 77. The delivery system of claim 33, wherein the occlusion device is selfexpanding.
  - 78. The delivery system of claim 33, wherein the occlusion device is a stent.
- 79. The delivery system of claim 33, wherein the tubular body is a flexible catheter body.
  - 80. An occlusion device delivery system comprising:
  - a tubular body including a distal portion;
- a releasably deployable occlusion device positioned on the distal portion of the tubular body; and

a distal tip member fixedly secured to the distal portion of the tubular body, the distal tip member configured to undergo bioabsorption or dissolution when the distal tip member is placed in vivo, wherein the distal tip member is configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorption or dissolution process, wherein the distal tip member does not hinder deployment of occlusion device prior to undergoing bioabsorpotion or dissolution.

81. The delivery system of claim 80, wherein the distal tip member further comprises a guidewire lumen.

- 82. The delivery system of claim 80, wherein the distal tip member is solid.
- 83. The delivery system of claim 80, wherein the distal tip member is configured to bioabsorb or dissolve in less than about 15 minutes in vivo.
- 84. The delivery system of claim 80, wherein the distal tip member is configured to bioabsorb or dissolve within a range of about 5 to about 10 minutes in vivo.
- 85. The delivery system of claim 80, wherein the distal tip member is configured to either bioabsorb or dissolve to a smaller profile.
- 86. The delivery system of claim 85, wherein the occlusion device comprises a distal opening when deployed, and the distal tip member, in the smaller profile, is configured to proximally pass through the distal opening of the deployed occlusion device when the tubular body is displaced in a proximal direction.
- 87. The delivery system of claim 80, wherein the distal tip member is configured to bioabsorb or dissolve substantially away.
- 88. The delivery system of claim 80, wherein the distal tip member has a substantially smooth transition at an edge of the tubular body.
- 89. The delivery system of claim 80, wherein the occlusion device is self-expanding.
  - 90. The delivery system of claim 80, wherein the occlusion device is a stent.
- 91. The delivery system of claim 80, wherein the tubular body is a flexible catheter body.
  - 92. An occlusion device delivery system comprising: a tubular body including a distal portion;

a releasably deployable occlusion device positioned on the distal portion of the tubular body, the occlusion device comprising a distal opening when deployed; and

a distal tip member fixedly secured to the distal portion of the tubular body distal to the occlusion device, the distal tip member configured to either bioabsorb or dissolve to a smaller profile when the distal tip member is placed in vivo, wherein the distal tip member is configured to remain fixedly secured to the distal portion of the tubular body during the entire bioabsorption or dissolution process, so that the distal tip member may proximally pass through the distal opening of the deployed occlusion device when the tubular body is displaced in a proximal direction.

- 93. The delivery system of claim 92, wherein the distal tip member further comprises a guidewire lumen.
  - 94. The delivery system of claim 92, wherein the distal tip member is solid.
- 95. The delivery system of claim 92, wherein the distal tip member is configured to bioabsorb or dissolve to the smaller profile in less than about 15 minutes in vivo.
- 96. The delivery system of claim 92, wherein the distal tip member is configured to bioabsorb or dissolve to the smaller profile within a range of about 5 to about 10 minutes in vivo.
- 97. The delivery system of claim 92, wherein the distal tip member has a substantially smooth transition at an edge of the tubular body.
- 98. The delivery system of claim 92, wherein the occlusion device is selfexpanding.
  - 99. The delivery system of claim 92, wherein the occlusion device is a stent.

- 100. The delivery system of claim 92, wherein the tubular body is a flexible catheter body.
- 101. The delivery system of claim 33, wherein the distal tip member is configured for not sliding off of the tubular body during the bioabsorption or dissolution process.
- 102. The delivery system of claim 80, wherein the distal tip member is configured for not sliding off of the tubular body during the bioabsorption or dissolution process.
- 103. The delivery system of claim 92, wherein the distal tip member is configured for not sliding off of the tubular body during the bioabsorption or dissolution process.
- 104. The delivery system of claim 33, wherein the distal tip member is configured for remaining intact during the bioabsorption or dissolution process.
- 105. The delivery system of claim 80, wherein the distal tip member is configured for remaining intact during the bioabsorption or dissolution process.
- 106. The delivery system of claim 92, wherein the distal tip member is configured for remaining intact during the bioabsorption or dissolution process.